

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION**

United States of America, <i>et al.</i> , <i>ex rel.</i>)	C/A No. 9:14-3699-RMG
Scarlett Lutz and Kayla Webster,)	
)	
Plaintiffs/Relators,)	
)	ORDER AND OPINION
v.)	
)	
Laboratory Corporation of America)	
Holdings,)	
)	
Defendant.)	
_____)	

Before the Court is Defendant’s motion to exclude the testimony of Relators’ expert witness, Raja Sekaran. (Dkt. No. 325.) Relators responded in opposition. (Dkt. No. 346.) For the reasons set forth below, the motion is granted in part and denied in part.

I. Background

This is a *qui tam* action in which the United States of America declined to intervene. Relators allege that Defendant violated the False Claims Act and Anti-Kickback Statute by submitting false claims to Government healthcare programs relating to blood draw services for tests referred by physicians to third-parties Health Diagnostic Laboratory (“HDL”) and Singulex, Inc., which Defendant knew were paying illegal inducements to the referring physicians. (Dkt. No. 50.)

II. Legal Standard

Rule 702 of the Federal Rules of Evidence governs expert witness testimony and provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702(a)-(d). “Implicit in the text of Rule 702 is a district court’s gatekeeping responsibility ‘to ensur[e] that an expert’s testimony both rests on a *reliable* foundation and is *relevant* to the task at hand.’” *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017) (emphasis in original) (quoting *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 597 (1993)).

First, “[w]ith respect to reliability, the district court must ensure that the proffered expert opinion is based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods.” *Nease*, 848 F.3d at 229 (internal quotation marks omitted). “As the Supreme Court has repeatedly explained, *Daubert v. Merrell Dow Pharmaceuticals, Inc.* [] offers district courts several guidepost factors that the court ‘may consider’ in assessing an expert’s evidentiary reliability to the extent that the factors are relevant to the specific facts of the case at hand.” *McKiver v. Murphy-Brown, LLC*, 980 F.3d 937, 959 (4th Cir. 2020) (emphasis in original). The “emphasis on the word ‘may’ [] reflects *Daubert*’s description of the Rule 702 inquiry as ‘a flexible one.’” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149 (1999) (quoting *Daubert*, 509 U.S. at 594). Factors that the district court may consider include: (1) “[w]hether a theory or technique . . . can be (and has been) tested”; (2) “whether the theory or technique has been subjected to peer review and publication”; (3) its “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the theory or technique has garnered “general acceptance.” *Daubert*, 509 U.S. at 593-94; accord *United States v. Hassan*, 742 F.3d 104, 130 (4th Cir. 2014).

“These factors may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his [or her] testimony.” *McKiver*, 980 F.3d at 959 (alteration in original) (internal quotation marks omitted). The *Daubert* list of factors is not “definitive or exhaustive.” *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003). Instead, “the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination.” *Kumho Tire Co.*, 526 U.S. at 142. For instance, courts have also considered whether experts “developed [their] opinions expressly for the purposes of testifying,” *Wehling v. Sandoz Pharms. Corp.*, 162 F.3d 1158 (Table), 1998 WL 546097, at *3 (4th Cir. Aug. 20, 1998) or “though research they have conducted independent of the litigation,” *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (on remand). This is because, at bottom, the “objective of [the *Daubert* gatekeeping requirement] . . . is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co.*, 526 U.S. at 152.

The reliability inquiry requires the district court to heed “two guiding, and sometimes competing, principles.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999). “On the one hand, . . . Rule 702 was intended to liberalize the introduction of relevant expert evidence,” *id.*, and “the trial court’s role as a gatekeeper is not intended to serve as a replacement for the adversary system,” *United States v. Stanley*, 533 F. App’x 325, 327 (4th Cir. 2013) (citing Fed. R. Evid. 702 advisory committee’s note), *cert. denied*, 134 S. Ct. 1002 (2014). Indeed, “[a]s with all other admissible evidence, expert testimony is subject to being tested by ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the

burden of proof.” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 596)). On the other hand, “[b]ecause expert witnesses have the potential to be both powerful and quite misleading, it is crucial that the district court conduct a careful analysis into the reliability of the expert’s proposed opinion.” *Fultz*, 591 F. App’x at 227 (internal quotation marks omitted). Thus, “given the potential persuasiveness of expert testimony, proffered evidence that has a greater potential to mislead than to enlighten should be excluded.” *Westberry*, 178 F.3d at 261. For this reason, the “proponent of the testimony” bears the burden of proving it is reliable. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). This reliability standard does not require proof “that the opinion is objectively correct, but only that the witness has sufficient expertise[.]” *TBL Collectibles, Inc. v. Owners Ins. Co.*, 385 F. Supp. 3d 1170, 1179 (D. Colo. 2018).

Second, in addition to being reliable, the testimony must be relevant, which, “of course, is evidence that helps ‘the trier of fact to understand the evidence or to determine a fact in issue.’” *Nease*, 848 F.3d at 229 (quoting *Daubert*, 509 U.S. at 591). The district court’s decision on the admissibility of expert testimony is reviewed for abuse of discretion. *United States v. Campbell*, 963 F.3d 309, 313 (4th Cir. 2020).

III. Discussion

Relators offer Sakaran as an expert witness on “the processes available for healthcare providers and other market participants to disclose fraud and abuse (‘F&A’) concerns to the government, including without limitation requests for fraud alerts and whether there are temporal limits on any such activities.” (Dkt. No. 325-9 at 3.) Their desire for this expert opinion arises from the parties’ argument over the significance of Defendant’s 2013 and 2014 anonymous requests to HHS-OIG for a special fraud alert on HDL’s conduct. Relators contend that Defendant made these special fraud alert requests anonymously and through outside counsel to point the finger at its co-conspirator, HDL, in order to obfuscate its own participation in the fraud

by providing blood draws on behalf of HDL. Defendant contends that the fact that it made special fraud alert requests belies any such inference and instead supports that it was acting as a concerned whistleblower of HDL's conduct. From this dispute arises the parties' interest in litigating, through dueling expert opinions, the topic of how healthcare providers can report fraud on the Government.

Defendant argues that Sekaran's testimony is "inadmissible" because he "improperly infringes upon the province of the Court to determine the meaning of relevant law" and "improperly speculates about LabCorp's state of mind." (Dkt. No. 325 at 5.) The Court rejects this argument, except as to one aspect of Sekaran's testimony, for the following reasons.

A. Sekaran Does Not Draw a Legal Conclusion or Testify on the Meaning of the Law.

Defendant argues that, in opining on the topic of processes available for healthcare providers and other market participants to disclose fraud, Sekaran impermissibly interprets the statutes and regulations that govern that process. It is well settled that it is the duty of the district court, not a party's expert, to state the meaning of the law. *United States v. Barile*, 286 F.3d 749, 760 (4th Cir. 2002.) "Opinion testimony that states a legal standard or draws a legal conclusion by applying law to facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 561-62 (4th Cir. 2006). "An opinion is not objectionable simply because it embraces an ultimate issue to be decided by the trier of fact, [but] such an opinion may be excluded if it is not helpful to the trier of fact under Rule 702." *Kopf v. Skyrms*, 993 F.2d 374, 377-78 (4th Cir. 1993). "Expert testimony that merely states a legal conclusion is less likely to assist the jury in its determination." *Barile*, 286 F.3d at 760. "The role of the district court, therefore, is to distinguish opinion testimony that embraces an ultimate issue of fact from opinion testimony that states a legal conclusion." *Id.* "The best way to determine whether opinion testimony contains

legal conclusions, is to determine whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular.” *Id.* (internal quotation marks omitted).

Defendant takes particular issue with three instances of Sekaran’s testimony, which the Court considers in turn. First, Sekaran testified in his deposition that the portion of the regulation governing “Solicitation of New Safe Harbors and Special Fraud Alerts” (published in December 2012), which states *To ensure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on February 26th, 2013*, means submission within the 60-day window “probably increases the chances of consideration, but it is not required” for consideration. In other words, Sekaran opines, although the statute provides that submissions will be ensured consideration if made inside the 60-day window, “I think [submitting] it within this window is helpful because it increases the likelihood that you’ll get substantive consideration, but it’s not a guarantee and it’s also not required.” *To ensure consideration*, Sekaran opines, is the OIG’s “expression of preference” that it receive submissions within the 60-day window, but it may also give consideration to submissions received outside the 60-day window. (Dkt. No. 325-1 at 50.)

The question is whether this opinion is an impermissible legal conclusion or if it is drawn from something inside Sekaran’s qualified expertise, such as his relevant experience. A review of the context of Sekaran’s testimony makes clear that he was testifying as to OIG’s practice when fielding received submissions, based on his experience working there from 1997 to 2002, and not opining on the meaning of the statute itself. For instance, Sekaran testified that his opinion was formed “based on my experience [at OIG]” and on his experience that OIG reviewers “want to manage their workload” over the course of the year “based on the volume of

material that they receive in response to these solicitations and the simple question of resources at the OIG.” Inferring that their yearly workload could not practically be condensed into a 60-day window, Sekaran testified he is “sure that [submissions are] all processed and there’s intake of everything.” This opinion is further supported, as he testified, by the fact that the statute also provides “special fraud alerts may be requested, quote, at any time.” Additionally, Sekaran testified that his opinion was based on his understanding of *consideration* to be OIG’s internal practice of “substantive engagement with the [] content [] of the request and proposals” and not the phrase’s definition as intended by the legislature or as a legal term of art. (Dkt. No. 325-1 at 50-51.) *See, e.g., Fagnant v. Johnson*, No. 4:11-cv-00302-RBH, 2013 WL 3354580, at *4 (D.S.C. July 3, 2013) (cautioning expert to “avoid the use of legal terms of art in conveying his opinions at trial” because “[s]uch characterizations will be excluded”).

Second, Defendant challenges when Sekaran opines in his report: “Even if LabCorp ‘missed the 2012 deadline’ for submitting comments in response to HHS-OIG’s 2012 annual solicitation (which was February 27, 2012), it was not required to ‘wait until 2013’ to submit its request for a Special Fraud Alert. LabCorp could have submitted a request to HHS-OIG for a Special Fraud Alert ‘at any time.’ There was no magic window.” (Dkt. No. 325-9 ¶ 60.) As above, Sekaran’s use of the phrase, “at any time,” is a quotation from Section 205 of the Health Insurance Portability and Accountability Act of 1996, which provides: “Any person may present, at any time, a request to the Inspector General for a notice which informs the public of practices which the Inspector General considers to be suspect or of particular concern under the Medicare program under title XVIII or a State health care program, as defined in section 1128(h) (in this subsection referred to as a ‘special fraud alert’).” (*Id.* ¶ 28.) Significantly, Sekaran here opines simply that Defendant could have submitted a special fraud request at any time—he does not

draw any opinion or conclusion from the statute as to whether the request would be considered or to what extent it would be effective to alert to HDL's fraud. Simply noting that the statute provides that a special fraud alert request can be made "at any time," and that this provision would apply to Defendant, is not an impermissible legal conclusion that would confuse, rather than aid, the jury. *See, e.g., Doe v. Coastal Carolina Univ.*, 4:18-cv-0268-SAL, 2021 WL 1651057, at *2 (D.S.C. Mar. 8, 2021) (holding that expert may mention statutory guidance and note that it informs standards and best practices, but "any statement that [defendant] failed to comply with [] guidance or the [statute] would amount to a legal conclusion").

Last, Defendant challenges when Sekaran opines that (1) "LabCorp could have, at any time, contacted HHS-OIG or any of the numerous other federal or state agencies I identify above to report the concerns it expressed in its February 2013 or February 2014 requests"; that (2) "[i]n my experience, HHS-OIG and the numerous other federal or state agencies I identify above would have welcomed such a report from LabCorp, at any time"; and that (3) "LabCorp could have sought an advisory opinion to receive guidance from the OIG on the payment of process handling fees." (Dkt. Nos. 325-9 ¶¶ 29-35, 61-62; 325-1 at 37.) Again, Sekaran is not here drawing a conclusion or opining that LabCorp should have made these submissions or that making them would have been more or less effective than the 2013 and 2014 special fraud alert requests it did make; rather, he is opining that, in his relevant experience, the options to make these submissions were also available, as a general matter. That opinion does not have "a greater potential to mislead than to enlighten" the jury. *Westberry*, 178 F.3d at 261.

B. Sekaran Does Not Speculate as to Defendant's State of Mind, Except for One Instance of Offering a Potentially Confusing Opinion on Defendant's Motivation.

Defendant argues that Sekaran impermissibly speculates as to its state of mind on several instances. Expert testimony cannot be based on "belief or speculation." *Nease*, 848 F.3d at 229.

The “question of intent is a classic jury question and not one for the experts.” *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004). A “defendant’s knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.” *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 553 (S.D. W.Va. 2014); *see also In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 607 (S.D. W.Va. June 2013) (“To the extent that Dr. Altenhofen might opine on Bard’s knowledge, motive, or intent based on corporate documents, such opinions are not properly the subject of expert testimony because these are lay matters.”).

Here, Defendant argues that Sekaran speculates as to its state of mind when he notes that the 2013 special fraud alert request “omits any reference to LabCorp’s own role in actually drawing the blood for HDL tests,” and then opines that, “[i]n my experience, by submitting its requests in this manner, LabCorp minimized the likelihood that HHS-OIG would scrutinize LabCorp’s own conduct in drawing blood for HDL tests.” (Dkt. No. 325-9 ¶ 63.) This is not an opinion on Defendant’s state of mind because it is devoid of any belief regarding what Defendant intended or was motivated to do. Rather, this is an opinion as to the effect on OIG—whether or not Defendant intended it—of Defendant anonymously submitting a special fraud alert that also did not state Defendant was working with HDL. Defendant also takes issue with Sekaran’s opinion that “it is self-evident” that, as his report provides, “by electing to submit the February 2013 and February 2014 [requests] anonymously, LabCorp avoided having to be publicly associated with these requests and avoided having its own conduct and motivation scrutinized by HHS OIG and others in the health care industry.” (Dkt. No. 325-1 at 55.) Again, Sekaran here is not offering any opinion on Defendant’s state of mind; he is merely offering his

opinion, based on his relevant experience, on the result of Defendant's act. This distinction is further highlighted by the following exchange during Sekaran's deposition:

Q: So, is it your view that LabCorp sought the fraud alert to bring concerns regarding HDL to the government?

A: Are you asking me about their motives, or - -

Q: I'm asking you, do you have an opinion as to why LabCorp sought a special fraud alert?

A: I do have an opinion. My report doesn't go into what their motivations were for doing it. But on its face, their special fraud alert requests discusses the HDL practice of providing compensation to referring physicians, and so on its face they wanted to bring that to the government's attention.

Q: Okay. Any other opinions as it relates to LabCorp?

A: No, no other opinions.

(*Id.* at 10.) Similarly, Sekaran was later asked and answered:

Q: So, as I understand you, you are attributing intent to Mr. King's seeking of the special fraud alert; is that correct?

...

A: No, I'm responding to your premise [. . .]

Q: So, I just want to understand your position. You think LabCorp sought a special fraud alert because LabCorp thought OIG would not issue guidance; is that correct?

...

A: I think that's a stronger statement. And again, I'd be willing to stand by, and again we're leagues beyond my expert report at this point. Now I'm giving you my opinions about the case. But I think that's an overly strong statement.

(*Id.* at 46.) Sekaran has, but clearly declines to offer as an expert, an opinion on Defendant's motive for anonymously submitting special fraud alerts that omitted reference to its work with

HDL. Instead, Sekaran cabins his opinion to the easily observable fact that Defendant wanted to communicate the information that it did communicate. While such testimony on what Defendant “wanted” to bring to the Government’s attention risks creeping into impermissible speculation on its state of mind, in this context it is a common-sense and generalizable observation that does not risk confusing the jury.

To be sure, Sekaran later testifies: “I do think another motivation [for the anonymous special fraud alert requests] was to get some credit, should it be needed later on, for having brought it to the government’s attention, but not too much credit, right, not enough to disclose themselves and their request. They didn’t want to go too far.” (*Id.* at 61.) If this opinion were offered in Sekaran’s capacity as an expert witness, it would be squarely inadmissible. But it was not; Sekaran immediately clarified that he was not offering it as an expert opinion by stating: “That’s my opinion. It’s not in my expert report. It’s far outside my expert report’s scope. You’ve asked me for my opinion after reading all these documents and thinking about this for some weeks, and that’s what I believe.” (*Id.*) Nevertheless, in an abundance of caution to avoid any confusion to the jury, the Court grants Defendant’s motion to exclude this particular testimony from Sekaran on Defendant’s motivation.

IV. Conclusion

For the foregoing reasons, Defendant’s motion to exclude the testimony of Relators’ expert witness Raja Sekaran (Dkt. No. 325) is **GRANTED IN PART and DENIED IN PART**. Defendant’s motion is denied, except it is partially granted only as to the specifically discussed opinion on Defendant’s “motivation.”

AND IT IS SO ORDERED.

s/ Richard Mark Gergel
Richard Mark Gergel
United States District Judge

June 3, 2021
Charleston, South Carolina